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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,156	08/27/2003	Rachel Meyers	MPI00-009P1RCP1DV1M	5012

7590 06/16/2005

MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,156	MEYERS ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C121:

I Claims 1-7, 12 and 18 drawn to an isolated nucleic acid molecule a host cell and a method of producing polypeptide by culturing said host cell expressing nucleic acid, and a kit classified in class 536, subclass 23.1,

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

II Claims 8-10 drawn to an isolated polypeptide, classified in class 435 subclass 69.1

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

III Claim 11 and 15 drawn to an antibody and a kit classified in class 530, subclass 387.1

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

IV Claim 13-14 drawn to a method for detecting a polypeptide using an antibody, classified in class 435, subclass 7.1.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

V Claims 16- 17 drawn to a method for detecting the presence of a nucleic acid molecule using nucleic acid probe classified in class 435, subclass 6.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

VI Claim 19-20 drawn to a method for identifying a test compound, which binds to polypeptide classified in class 435, subclass 7.22.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

VII Claim 21 drawn to a method for modulating the activity of polypeptide using cells that express said polypeptide classified in class 435, subclass 7.21.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

VIII Claim 22 drawn to a method for identifying a compound, which modulates the activity of a polypeptide class 435, subclass 7.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

2. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP. 806.04, MPEP. 808.01). In the instant case the different inventions are different products. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, are patentably distinct products, which are different structurally, functionally, and biochemically. Invention I is drawn to a DNA (nucleic acid molecule) which is made of nucleic acids. Invention II is drawn to a polypeptide, which is made of amino acids. Thus, invention I and II are structurally different. Invention III is drawn to an antibody and is structurally distinct from Inventions I and II since it has an inherent affinity, avidity, and specificity.

3. Inventions IV, V, VI, VII and VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effect (MPEP. 806.04, MPEP. 808.01). In the instant case the different inventions are different methods. The inventions are distinct, each from the other because of the following reasons: Inventions IV, V, VI, VII and VIII different to each other because they use patentably distinct and different products which are different structurally, functionally and biochemically. Thus, Inventions IV, V, VI, VII and VIII are patentably distinct methods requiring different reagents, method steps that result in a different outcome

4. For each group of inventions I-VIII as stated above, restriction to one of the following SEQ.ID.NO is also required under 35 USC 121. Therefore, election is required of one of groups I – VIII and one of SEQ ID NO: 4-18 (Please indicate associated ATCC Accession number) Inventions SEQ ID NO: 1 – 113 (associated ATCC Accession number) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polynucleotides, polypeptide and antibodies. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO and its associated Acession number. Restriction is deemed proper because these products appear to constitute patentably distinct inventions. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO and indicate the associated Accession number.

4. Inventions I and V /VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

806.05(h)). In the instant case the product as claimed can be used in a materially different process of V and VII

5. Inventions II and VI//VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process of VI and VIII

6. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process immuno chromatography for purifying the antigens.

7. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821 .04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection

or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1 .1 16., amendments submitted after allowance are governed by 37 CFR 1 .312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 1 12. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C.121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number for submission of before-final amendments is (703) 872-9306. The Right Fax number for submission of after-final amendments is (703) 872-9307.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600